

Notice of Allowability

Application No.

09/369,941

Examiner

Michael C. Wilson

Applicant(s)

KENSIL, CHARLOTTE A.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 8-2-05 and RCE filed 9-1-05.
2. ☒ The allowed claim(s) is/are 19,21-28,63-78,90,92-103,105-112,114,128 and 150-161.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 11-7-05
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____



**MICHAEL WILSON
PRIMARY EXAMINER**

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-1-05 has been entered.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

The amendment filed 8-2-05 has been entered. Applicant's arguments filed 8-2-04 have been fully considered and are persuasive.

Claims 1-18, 20, 29-62, 79-89, 91, 104, 113, 115-127 and 129-149 have been canceled. Claims 150-161 have been added. Claims 19, 21-28, 63-78, 90, 92-103, 105-112, 114, 128 and 150-161 are pending and under consideration in the instant office action.

Election/Restrictions

Claims 19, 21-28, 63-78, 90, 92-103, 105-112, 114, 128 and 151-161 are under consideration in the instant office action as they relate to a composition comprising a) saponin and b) an immunostimulatory oligonucleotide, and to a method of using such a composition (Group II). The claims are not being examined as they relate to a composition comprising a) saponin, b) an immunostimulatory oligonucleotide, and c) an antigen, or methods of using such a composition. For examination purposes a "nucleic

acid sequence encoding an antigen" is not an antigen because antigens are proteins, and because nucleic acid sequences are materially distinct and separate than proteins.

Claim Objections

The objection in claims 109 has been withdrawn in view of the amendment.

Claim Rejections - 35 USC 112

New Matter

The rejection of claims 64, 67, 68, 70, 72, 74, 76, 90, 103 and 127 regarding new matter (administering a saponin; an immunostimulatory oligonucleotide; and a nucleic acid molecule encoding an antigen) was withdrawn in the previous office action because the specification does not have to disclose *ipsis verbis* what is being claimed.

The rejection regarding the phrase "wherein the nucleic acid comprising a nucleotide sequence encoding the antigen is administered to the individual within 2 days of said administering of the immune adjuvant" in claims 113 and 127 as being new matter has been withdrawn because the claims have been canceled.

The phrase "wherein the saponin and immunostimulatory oligonucleotide have a synergistic adjuvant effect" in claims 19, 63, 64, 69, 71, 73 and 75 can be found on pg 14, lines 4-6. A number of combinations of QS-21 and immunostimulatory oligonucleotide of SEQ ID NO: 1 or 2 (1758 and 1826) having a synergistic adjuvant effect were disclosed in the specification as originally filed (see pg 12-21 of the office action sent 3-2-05; Examples 1, 3 and 4; Fig. 1, 3, 5). One of skill could have readily tested to see which combinations of QS-21 and immunostimulatory oligonucleotide had a synergistic effect. Fig. 2 of Kensil (AIDS Research Rev., 1993, Vol. 3, Koff, ed., New

York, NY, pg 379-390, filed with the Kensil Declaration on 4-26-04) showed the structural similarities of QS-17, -18, and -21. Fig. 3 of Kensil (J. Immunol., January 15, 1991, Vol. 146, No. 2, pg 431-437, filed with the Kensil Declaration on 4-26-04) showed the functional adjuvant similarities of QS-7, -17, -18 and -21 (pg 434). Without evidence to the contrary, certain combinations of QS-7, -17, -18 and -21 with SEQ ID NO: 1 or 2 or other immunostimulatory oligonucleotide would also be expected to have a synergistic adjuvant effect as claimed, which could easily be tested by one of skill in the art. As such, the genus claimed has support in the specification as originally filed taken with the art at the time of filing.

Claim Rejections - 35 USC 103

The rejection of claims 19, 21-27, 63-68, 73-77, 90, 95-98, 100-102, 114 and 128 under 35 U.S.C. 103(a) as being unpatentable over Weiner (Sept. 1997, PNAS, Vol. 94, pages 10833-10837) in view of Kensil (1996, Critical Reviews in Therapeutic Drug carrier Systems, Vol. 13, No. 1 and 2, pages 1-55) has been withdrawn in view of the amendment. The compositions in the products and methods claimed are now limited to those in which the saponin and immunostimulatory oligonucleotide have a synergistic adjuvant effect. One of ordinary skill would not have reasonably expected the saponin of Kensil combined with the oligonucleotide of Weiner would have a synergistic adjuvant effect as claimed.

The rejection of claims 19, 21, 24, 25, 27, 28, 65, 67, 69, 70, 73-77, 90, 95-98, 100-102, 114 and 128 under 35 U.S.C. 103(a) as being unpatentable over Weiner (Sept. 1997, PNAS, Vol. 94, pg 10833-10837) in view of Kensil (1996, Critical Reviews in Therapeutic Drug carrier Systems, Vol. 13, No. 1 and 2, pg 1-55) has been withdrawn in view of the amendment. The compositions in the products and methods claimed are now limited to those in which the saponin and immunostimulatory oligonucleotide have a synergistic adjuvant effect. One of ordinary skill would not have reasonably expected the saponin of Kensil combined with the oligonucleotide of Weiner would have a synergistic adjuvant effect as claimed.

The rejection of claims 19, 21-27, 63-68, 71-78, 90, 95-98, 100-102, 114 and 128 under 35 U.S.C. 103(a) as being unpatentable over Chu (Nov. 17, 1997, J. Exp. Med., Vol. 186, pg 1623-1631) in view of Kensil (Kensil, 1996, Critical Reviews in Therapeutic Drug Carrier Systems, Vol. 13, No. 1 and 2, pg 1-55) has been withdrawn in view of the amendment. The compositions in the products and methods claimed are now limited to those in which the saponin and immunostimulatory oligonucleotide have a synergistic adjuvant effect. One of ordinary skill would not have reasonably expected the saponin of Kensil combined with the oligonucleotide of Chu would have a synergistic adjuvant effect as claimed.

The claims are free of the prior art of record because the prior art did not teach or suggest a composition comprising a saponin having immune adjuvant activity and an

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immunostimulatory oligonucleotide having at least one unmethylated CpG dinucleotide, wherein the immunostimulatory oligonucleotide is not part of a DNA vaccine, wherein the saponin and immunostimulatory oligonucleotide have a synergistic adjuvant effect. It is noted that the limitation of a CpG motif having the formula 5'X₁CGX₂3' in claim 27, 98 and 111 was not searched. The nucleic acid is so small and may be part of any plasmid, which is very large in comparison, and cannot be adequately searched on computer databases or by eye.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It

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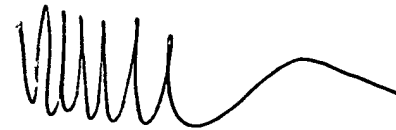
also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

A handwritten signature in black ink, consisting of a series of vertical, slightly wavy lines followed by a long, sweeping horizontal stroke that curves upwards at the end.

MICHAEL WILSON
PRIMARY EXAMINER